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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,160	04/23/2001	Kristiina Ylihonko	1574/49849	9775

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Evenson McKeown Edwards & Lenahan
1200 G Street N W Suite 700
Washington, DC 20005

EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/830,160	YLIHONKO ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. By virtue of a preliminary amendment filed on April 23, 2001, which amended Claims 3, 7, and 12 and added new Claims 16-26, Claims 1-26 are pending in the instant application.

Claim Interpretation for Purposes of Restriction

2. The following is an interpretation of the pending claims, where necessary, that has led to the below restriction. Should this interpretation be argued by Applicants to be in error, a supplemental restriction requirement may be necessary.

Claim 2, which is improperly dependent, is the broadest claim. Claim 1 is drawn to DNA comprising the entire gene cluster from *S. nogalater* while Claim 2 is drawn to DNA comprising variants of the entire gene cluster. Thus, the scope of Claim 2 must have a special technical feature that adds to the prior art to have unity of invention.

Restriction

3. Restriction is required under 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7-11, and 16-22, drawn to a DNA sequence related to the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*, plasmids thereof, and methods of using said DNA.

Group II, claim(s) 5, drawn to pSY42.

Group III, claim(s) 6, drawn to pSY43.

Group IV, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogJ gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group V, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogA gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group VI, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoaM gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group VII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogN gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group VIII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogG gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group IX, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogC gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group X, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogK gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XI, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoaL gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoK gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XIII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogD gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XIV, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoW gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XV, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snogE gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XVI, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoL gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XVII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoO gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

Group XVIII, claim(s) 12-15 and 23-26, drawn to methods of producing aclacinomycin using at least a snoaF gene of the full-length gene cluster for the anthracycline (nogalamycinone) biosynthetic pathway from *S. nogalater*.

4. The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature of Group I relies on the structural features (related to SEQ ID NO:1) of the full-length gene cluster of the *S. nogalater* genome noted (see Claim 2). This technical feature is shared by the methods in Group I because the entire gene cluster is used in said methods. However, this technical feature of not shared by plasmids pSY42 or pSY43 (Groups II and III) which contain only portions of the full-length gene cluster. Moreover, this technical feature is also not shared with the methods of Groups IV-XVIII which are drawn to the use of only portions of the gene cluster as described by particular genes (open reading frames).

The portions of the gene cluster are distinct from the full-length gene cluster in both structure and function. The structure is clearly distinct as one is a substructure of the other and

the particulars of the structure are distinct from the particulars of the substructure. The function is also distinct because while the full-length gene cluster encodes enzymes to produce a whole anthracycline (nogalomycin), the individual open reading frames encode enzymes to catalyze a single reaction of a single intermediate. Said intermediates are independent of the entire pathway and have distinct structures and functions with respect to the whole anthracycline.

Election

5. A telephone call was made to Herbert Cantor on June 11, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
June 11, 2003